Remarks

Claims 1-4, 7-30, 33-35, and 54-63 are pending upon entry of the foregoing amendments. Claims 1, 55, and 56 are the independent claims.

Amendments to the Claims

Claim 1 has been amended to expressly recite that the means for disintegrating by electrothermal ablation comprises (i) an electrical input lead and an electrical output lead which are electrically connected to at least one of said reservoir caps, (ii) a power source, and (iii) a control means for controlling application of an electric current from the power source through said at least one of the reservoir caps, via the input and output leads. Support for the amendment is found, for example, at page 19, line 26 to page 20, line 1:

> The reservoir cap is operably (i.e. **electrically) connected** to an electrical **input lead** and to an electrical **output lead**, to facilitate **flow of an electric current through the reservoir cap**. When an effective amount of an electrical current is applied through the leads and reservoir cap, the temperature of the reservoir cap is locally increased due to resistive heating, and the heat generated within the reservoir cap increases the temperature sufficiently to cause the reservoir cap to be electrothermally ablated (i.e., ruptured).
> (emphasis added).

Support also can be found, for example, at page 21, line 30 to page 22, line 19, and pages 24-25.

Claim 55 has been amended to specify that the reservoir cap is metal. Support for this amendment is found, for example, at page 19, line 23. Claim 25 has been canceled.

Rejection Under 35 U.S.C. § 102

Claims 1-4, 7-14, 16-30, and 33-34 were rejected under 35 U.S.C. § 102(a) and § 102(e) as anticipated by U.S. Patent Publication 2002/0072784 by Sheppard Jr. et al. (hereinafter "Sheppard"). The rejection is traversed.

Applicants maintain that claim 1 in its previous form, if *properly* construed and giving terms their broadest *reasonable* interpretation, is not anticipated by Sheppard. Nevertheless, Applicants have amended claim 1 as suggested by the examiner to positively recite features for flowing electric current through the reservoir cap to cause the generation of heat within the reservoir cap in an amount effect to electrothermally ablate, i.e., rupture, the reservoir cap. These features are neither explicit nor inherent in Sheppard. The rejection of claim 1 therefore cannot stand.

Furthermore, Sheppard fails to anticipate any of claims 26-28. Sheppard does not disclose one or more electrodes or sensors are on an outer surface of a hermetically sealed encasement containing the drug delivery module and the microcontroller, as required by Applicants' claim 26. Sheppard fails to disclose one or more electrodes or sensors extend a distance from a hermetically sealed encasement containing the drug delivery module and microcontroller, as required by Applicants' claims 27. In addition, no where in Sheppard it is disclosed that a flexible catheter connects the one or more electrodes to the encasement, as is required by Applicants' claim 28.

Rejections Under 35 U.S.C. § 103

Claims 55-63 were rejected as anticipated by, or in the alternative, obvious over Sheppard. Claims 15 and 54 were rejected as obvious over Sheppard in view of U.S. Patent 6,112,116 to Fischell et al (hereinafter "Fischell"). Claim 35 was rejected as obvious over Sheppard in view of U.S. Patent 6,726,920 to Theeuwes et al. (hereinafter "Theeuwes"). The rejections are respectfully traversed.

The Examiner misunderstands Sheppard, and the rejections therefore are based on factual errors.

The first error is the contention at page 7 of the office action, wherein the Examiner asserts that there necessarily would be conducting leads "in order to provide the reservoir cap with electrical energy." That is incorrect. Paragraph [0026] in Sheppard describes disintegration of a reservoir cap by an electro*chemical* mechanism in which there is only a **single** electrical lead to anodic reservoir cap and a **separate** cathode. There is not a *pair* of electrical leads connected to the reservoir cap in that embodiment because a surrounding conductive fluid completes an electrical circuit. See ¶4, Rule 132 Declaration of Dr. Santini.

The second error is the Examiner's misleading and misplaced reliance paragraph [0027] in Sheppard. That pragraph is not describing *disintegrating or rupturing* of a reservoir cap, but merely discloses *modulating the porosity* of a polymer. A porosity modulation process is different from electrothermal ablation. The Examiner inexplicably alleges in the Office Action at page 7, second paragraph, that the electrically responsive polymer would disintegrate upon application of electrical energy. That cannot be true, because the material cannot both have a porosity that is modulated and disintegrate. One skilled in the art would not confuse modulation and disintegration.

It is also noted that claim 55 as presently amended specifies that the reservoir cap is metal. Sheppard's disclosure of modulating the porosity of a polymer is therefore not relevant to a metal reservoir cap.

The third error is that the Examiner has improperly ignored evidence of record that plainly refutes the Examiner's contentions. The Rule 312 Declaration by Dr. Santini unequivocally states that Sheppard does not disclose electrothermal ablation of a reservoir cap. Yet, the Examiner persists with an untenable interpretation of Sheppard and a technically unreasonable interpretation of the term "electrothermal ablation."

Sheppard and Fischell, Sheppard and Theeuwes

As explained above, Sheppard fails to disclose or suggest devices that include means for disintegration of reservoir caps by electrothermal ablation. Neither Fischell nor Theeuwes supplement this deficiency, for the reasons of record.

Conclusions

Applicants respectfully submit that the claims are patentable over the prior art of record. Prompt allowance of each of claims 1-4, 7-30, 33-35, and 54-63 is therefore respectfully solicited.

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,

/Kevin W. King/
Kevin W. King
Reg. No. 42,737

Date: October 16, 2008

SUTHERLAND ASBILL & BRENNAN LLP
999 Peachtree Street, NE
Atlanta, Georgia 30309-3996
(404) 853-8068
(404) 853-8806 (fax)